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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,365	01/18/2002	Mayumi Kotani	SAEGU92.001APC	7977

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EXAMINER

VANIK, DAVID L

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 06/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/937,365

Applicant(s)

KOTANI ET AL.

Examiner

David L. Vanik

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 10-22 and 24-42 is/are pending in the application.
- 4a) Of the above claim(s) 25-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 10-22 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Receipt is acknowledged of applicant's Request for Continued Examination filed on 3/21/2005. Receipt is also acknowledged of applicant's Response to Election/Restriction filed on 5/23/2005. Applicant's arguments with respect to claims 1, 10-22, 24 have been considered but are moot in view of the new ground(s) of rejection.

Election/Restrictions

Applicant's election without traverse of claims 1, and 10-24 in the reply filed on 5/23/2005 is acknowledged. Examiner also acknowledges applicant's election of oral administration as a species. Because claim 23 has been cancelled by applicant, it will be withdrawn from consideration.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 21-22 are rejected under 35 U.S.C. 102(b) as being anticipated by WO98/42188 ('188).

'188 disclose a medicinal composition comprising kaempferol-3-glucoside (page 12, lines 3-4). The treatment of pollinosis is considered a future intended use and, as such, is given no patentable weight in a composition claim.

Claims 21 and 22 are product-by-process claims. As such, claims 21 and 22 will be treated as product claims and not as method claims. By disclosing a composition comprising kaempferol-3-glucoside, the composition advanced by '188 anticipates the instant claims 21 and 22 (page 12, lines 3-4).

The claims are therefore anticipated by WO98/42188 ('188).

Claim 1, 18-22 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 4,808,574 ('574).

'574 disclose a medicinal composition comprising kaempferol-3-glucoside (column 2, line 61). The kaempferol-3-glucoside-based compositions further comprise a carrier, ethanol (Claims 1 and 2). According to '574, kaempferol-3-glucoside can be combined with a food product, an alcoholic beverage (Claims 1 and 2). The treatment of pollinosis is considered a future intended use and, as such, is given no patentable weight in a composition claim.

Claims 21 and 22 are product-by-process claims. As such, claims 21 and 22 will be treated as product claims and not as method claims. By disclosing a composition comprising kaempferol-3-glucoside, the composition advanced by '574 anticipates the instant claims 21 and 22 (column 2, line 61).

The claims are therefore anticipated by US Patent 4,808,574 ('574).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 10-22, and 24 rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 4,808,574 ('574) in view of Fukumoto et al (Antianaphylactic Effects of the Principal Compounds from the White Petals of *Impatiens balsamina* L., Phytotherapy Research, Vol. 10., 202-206 (1996)) and JP110296561A ('561).

The teachings of '574 are enumerated above. '574 teaches a medicinal composition comprising kaempferol-3-glucoside dispersed in a food product, a beverage (Claims 1 and 2). The beverage is orally consumed.

'574 does not teach a method of using kaempferol-3-glucoside to treat pollinosis.

Fukumoto et al. teach medicinal compositions isolated from plants (see page 204, column 1). Said isolated plant compositions have been found to alleviate dermatological lesions, including dermatitis related to the disorder urticaria (see page 202, column 1). Also, according to Fukumoto et al., compounds isolated from the white petals of *Impatiens balsamina* L., such as kaempferol-3-glucoside, have the ability to inhibit IgE-mediated anaphylaxis in mice (see page 202, column 1). It has also been demonstrated that kaempferol-3-glucoside inhibits the release of IgE-promoted histamine from mast cells (see Page 205, column 2).

According to applicant's specification, pollinosis is accompanied by a rise in IgE levels (page 14, lines 10-12 and page 5, lines 17-22). This finding is also indicated by the literature. For example, as set forth in '561, inhibition of IgE production is an effective method for treating either pollinosis or anaphylaxis (see abstract). Thus, compositions that have the ability to inhibit IgE production can be used to treat pollinosis. Because compounds that inhibit IgE production, such as kaempferol-3-glucoside, can be used to effectively treat allergy-related disorders, such as pollinosis, one of ordinary skill in the art would have been motivated to treat pollinosis with a composition comprising kaempferol-3-glucoside. Based on the teachings of both Fukumoto et al. and '561, there is a reasonable expectation that kaempferol-3-glucoside, an IgE inhibiting compound, would effectively treat allergy-related disorders, such as pollinosis. As such, it would have been obvious to one of ordinary skill in the

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art at the time the invention was made to use kaempferol-3-glucoside to treat pollinosis as indicated by the teachings of Fukumoto et al and '561.

With respect to the claimed concentrations and dosage, absent a clear showing of criticality, the determination of particular concentrations and dosage is within the skill of the ordinary worker as part of the process of normal optimization.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Application 2002/0068094 A1 is cited as a patent of interest in its disclosure of a composition comprising kaempferol (paragraph 0021). The composition can be used in a method to treat pollinosis (paragraph 0036).

Correspondence

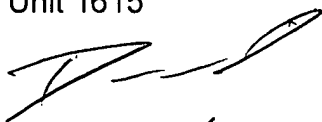
Any inquiry concerning this communication or earlier communications from the examiner should be directed to David L. Vanik whose telephone number is (571) 272-3104. The examiner can normally be reached on Monday-Friday 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carlos Azpuru, can be reached at (571) 272-0588. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Vanik, Ph.D.
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6/8/08
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